

### **REMARKS**

Claims 11-16 and 38-40 are pending and at issue in this application. Of these, claim 11 is independent and claims 38-40 are added by this amendment. Claims 1-10 are cancelled without prejudice. Applicant respectfully requests reconsideration and favorable action in this case.

Claim 11 is amended to recite, in part, an apparatus for extracting bone material from an extraction site, comprising a flexible shaft with a proximal end disposed in the cavity and a distal end extending beyond the cavity; an abrading head attached to the distal end of the shaft; a conduit extending through the shaft and abrading head, the conduit fluidly communicating with the passageway; and an actuator coupled to the distal end of the shaft, wherein the shaft is free to deflect radially with respect to a connection to the actuator. The radially deflecting shaft that protrudes from the cavity is supported in the specification at least on page 12 and in Figure 6 of the application.

Claim 15 is amended to recite that the abrading head comprises a bur and the actuator causes the shaft to move in a reciprocating motion. This is supported in the specification at least on page 12.

Claim 38 is added and recites that a second end of the suction tube is connected to a vacuum source. This is supported in the specification at least on page 7.

Claim 39 is added and recites that the collection device comprises a container in fluid communication with the suction tube. This is supported in the specification at least on page 9.

Claim 40 is added and recites that the housing defines a second passageway for passing irrigation fluid to the extraction site, the apparatus further comprising a source of irrigation fluid in fluid communication with the second passage. This is supported in the specification at least on page 6.

Because claims 1-10 are cancelled by this amendment, the rejection of claims 1-4 as obvious over Harrel (U.S. Patent No. 5,122,153) in view of Bonutti (U.S. Patent No. 5,269,785), the rejection of claim 5 as obvious over Harrel in view of Bonutti and Abbott (U.S. Patent No. 4,176,453), the rejection of claims 6-9 as obvious over Del Rio (U.S. Patent No. 5,601,560) in view of Harrel, and the rejection of claim 10 as obvious over Del Rio in view of Harrel and Abbott are moot.

Applicant respectfully traverses the rejection of claims 11 and 14 as anticipated by Harrel. Each of pending claims 11 and 14 recites a flexible shaft with a proximal end disposed in a cavity and a distal end extending beyond the cavity wherein the shaft is free to deflect radially with respect to a connection to an actuator, and a conduit extending through the shaft and abrading head. Harrel does not disclose a flexible shaft extending beyond a cavity, wherein the shaft is free to deflect radially with respect to a connection to an actuator, or a conduit extending through the shaft and abrading head. Therefore, Harrel cannot anticipate claims 11 or 14, or claims 12-13 and 38-40 which depend from claim 11.

While Harrel discloses a tissue removing instrument including a rotatable shaft, Harrel does not disclose a flexible shaft free to deflect radially with respect to a connection to an actuator. Furthermore, Harrel does not disclose, in any manner, a conduit through the shaft and abrading head.

Applicant respectfully traverses the rejection of claims 11, 14 and 15 as obvious over Harrel in view of Bonutti. Each of pending claims 11-16 and 38-40 recites a flexible shaft with a proximal end disposed in a cavity and a distal end extending beyond the cavity, wherein the shaft is free to deflect radially with respect to a connection to an actuator. As discussed above, Harrel does not disclose a flexible shaft with a proximal end disposed in a cavity and a distal end extending beyond the cavity, wherein the shaft is free to deflect

radially with respect to a connection to an actuator. Bonutti similarly fails to disclose or suggest such a radially deflecting shaft extending from a cavity. Therefore, no combination of Harrel or Bonutti can render the pending claims obvious.

While Bonutti discloses a flexible shaft, it does not disclose a flexible shaft extending beyond a cavity of a housing, wherein the shaft is free to deflect radially with respect to a connection to an actuator, as specified in claim 11. Instead, Bonutti discloses a flexible shaft that can be shaped, prior to insertion and operation of a drill, for guiding a cutting tip through a percutaneous insertion point towards a target site. Once insertion occurs and drilling operation begins, the shaft shape is fixed. The pending claims, on the other hand, recite a flexible drive shaft that protrudes from a housing cavity wherein the flexible shaft is free to deflect radially with respect to a connection to an actuator during operation of the drill. In fact, it is during operation of the drill that the shaft is allowed to whip around in a radial motion for the purpose of increasing the harvest of bone material from a single extraction site. Moreover, Bonutti does not disclose a flexible shaft extending beyond a cavity. It follows, therefore, that Bonutti does not disclose the shaft recited by the pending claims.

One of ordinary skill would not be motivated by Bonutti to modify Harrel to arrive at the claimed subject matter. Bonutti does not recognize the need for a radially deflecting shaft extending from a cavity to increase harvest of bone material from a single extraction site. Instead, it is primarily concerned with providing a pre-shaped shaft for guiding a cutting tip to a desired location from an insertion point, not with providing a radially deflecting shaft for increasing harvest. Moreover, using a radially deflecting shaft extending from a cavity would render the Bonutti device inoperable for its intended purpose. The Bonutti shaft is intended to guide and precisely position a cutting tip over a target location to minimize surrounding tissue damage. The flexible shaft of the pending claims, on the other hand, is intended to

affect as much bone material as possible surrounding an extraction site. A radial deflection of the flexible shaft and cutting tip of Bonutti would cause severe tissue damage, which Bonutti is intended to prevent. Consequently, Bonutti cannot teach or even suggest a modification of its apparatus to include a flexible shaft that extends beyond a cavity and deflects radially about a connection to an actuator.

It is clear that the prior art must make a suggestion of or provide an incentive for a claimed combination of elements to establish a prima facie case of obviousness. See, *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992); *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. 1985). This principle holds true even if the applied art could be modified to produce the invention recited by the pending claims. See, *In re Mills*, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990); *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984) ("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.") Because Bonutti does not disclose or even suggest the desirability of using a flexible shaft that extends beyond a cavity and deflects radially with respect to a connection to an actuator, Bonutti cannot render any of the pending claims obvious, alone or in combination with Harrel.

Applicant respectfully traverses the rejection of claims 11, 12, and 14 as obvious over Harrel in view of Keith (U.S. Patent No. 5,667,490). Keith fails to supply the deficiencies noted above with respect to Harrel. Specifically, Keith does not disclose or suggest a flexible shaft that extends beyond a cavity and deflects radially with respect to a connection to an actuator. Instead, Keith teaches a drive assembly for an ablation device that includes a drive shaft made of a tightly wound coil used to provide flexibility to the drive shaft. Accordingly, the combination of Harrel and Keith fails to render the claims obvious, and the rejection based thereon must be withdrawn.

Applicant respectfully traverses the rejection of claims 11, 13, and 14 as obvious over Harrel in view of Barber (U.S. Patent No. 4,541,423). Barber also fails to supply the deficiencies noted above with respect to Harrel. Specifically, Barber does not disclose or suggest a flexible shaft that extends beyond a cavity and deflects radially with respect to a connection to an actuator. Instead, Barber discloses a drilling apparatus comprising a flexible shaft composed of a semi-rigid material which is bendable to a desired curvature, but similar to Bonutti, is fixed during insertion and operation of the drill. Accordingly, the combination of Harrel and Barber fails to render the claims obvious, and the rejection based thereon must be withdrawn.

Applicant respectfully traverses the rejection of claims 11, 14, and 16 as obvious over Harrel in view of Del Rio (U.S. Patent No. 5,601,560). Del Rio fails to supply the deficiencies noted above with respect to Harrel. Specifically, Del Rio does not disclose or suggest a flexible shaft that extends beyond a cavity and deflects radially with respect to a connection to an actuator. Instead, Del Rio discloses a surgical instrument comprising a motor and a spindle that is releasably coupled to the motor. Accordingly, the combination of Harrel and Del Rio fails to render the claims obvious, and the rejection based thereon must be withdrawn.

**CONCLUSION**

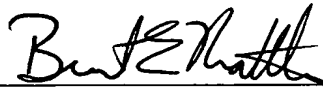
Applicant submits that this case is in a condition for immediate allowance. For the foregoing reasons, Applicant respectfully requests reconsideration and allowance of claims 11-16 and 38-40.

If there are matters that can be discussed by telephone to further the prosecution of this application, Applicants respectfully request that the Examiner call its attorney at the number listed below.

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